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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/270,480	03/15/1999	MARKKU AHOTUPA	00013/7075	2552

7590 01/18/2002

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EXAMINER

GITOMER, RALPH J

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 01/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/270,480

Applicant(s)

Ahotupa

Examiner

Ralph Gitomer

Art Unit

1623



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 15, 1999
- 2a) This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) All b) Some\* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachments

- 15) ☒ Notice of References Cited (PTO 816)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO 916)
- 17) Notice of Informal Patent Application (PTO 152)
- 18) Other \_\_\_\_\_

No Declaration is found in the file.

The following is a quotation of 35 U.S.C. 103(a) which forms  
5 the basis for all obviousness rejections set forth in this Office  
action:

10 (a) A patent may not be obtained though the invention is not identically  
disclosed or described as set forth in section 102 of this title, if the  
differences between the subject matter sought to be patented and the prior  
art are such that the subject matter as a whole would have been obvious at  
the time the invention was made to a person having ordinary skill in the  
art to which said subject matter pertains. Patentability shall not be  
negated by the manner in which the invention was made.

15 Claims 1-6, 16-19, 25 are rejected under 35 U.S.C. 103(a) as  
being unpatentable over the combination of Wieland in view of  
Vasankari.

No single point of novelty is seen in the claims. And no  
background of the invention is provided to assist in  
20 understanding the specification as originally filed. The  
claimed invention is directed to a kit to perform four steps to  
determine oxidizability of LDL's:

1. Separate LDL from plasma with a heparin solution to  
precipitate lipids.
- 25 2. Separate LDL from lipids with chloroform:methanol solution.
3. Determining baseline level of conjugate dienes in the lipid

Each of these steps is well known for its art recognized function. To combine each known step with the expected result would have been obvious. And to perform known steps with a kit is not novel. One would be motivated to incorporate the claimed hardware and reagents into a kit with the expectation of commercial success because advantages include ease of automation, small volume of plasma samples, faster analysis time, increased sensitivity and the potential for an increased degree of standardization.

Wieland (J of Lipid Res) entitled ❖A Simple Method for Precipitation of Low Density Lipoproteins❖ teaches on page 904 column 2 first full paragraph, LDL's can be precipitated with heparin where VLDL and HDL remain in solution. LDL lipids may then be determined by various techniques after selective precipitation.

The claims differ from Wieland in that they then determine LDL lipids by extracting with chloroform:methanol, then cyclohexane.

Vasankari (Clinica Chimica Acta) entitled ❖Measurement of Serum Lipid Peroxidation During Exercise using Three Different Methods❖ teaches on page 65, extracting lipids from serum samples with chloroform:methanol, then cyclohexane.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the LDL lipids determination as described by Wieland with the method of Vasankari because there are a number of known methods of extracting the lipid fraction and any of the known methods would have the expected result. To select the method of Vasankari would have been obvious because it would have the expected result.

Regarding claim 25 directed to a container containing heparin and instructions, no weight is given in a kit claim to any instructions which may accompany the reagents or apparatus of the kit. Containers of heparin are known.

Claims 7-15, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wieland in view of Vasankari as applied to claims 1-6, 16-19, 25 above, and further in view of each of Seccia and Valkonen.

The teachings of Wieland and Vasankari and their applicability to the instant invention have been discussed above.

The claims further differ from the above references in that they specify determining the antioxidant potential of the separated dienes with ABAP.

Seccia (Clinical Chemistry) entitled "Suitability of

amidinopropane)HCl for determining LDL oxidation.

Valkonen (J of Lipid Res) entitled ❖Spectrophotometric Assay for Total Peroxyl Radical Trapping Antioxidant Potential in Human Serum❖ teaches on page 823 column 1 in the abstract, 2,2'-

5 diazobis(2-amidinopropane)HCl for measuring peroxyl radical trapping potential (TRAP).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine TRAP in the method taught by Wieland and Vasankari with the presently claimed  
10 reagent ABAP as taught by each of Seccia and Valkonen because determining the antioxidant potential of separated dienes with ABAP is taught by each of Seccia and Valkonen. And they also teach that the dienes determined must be previously separated from plasma. The present claims are directed to a different  
15 method of separation from that of Seccia and Valkonen. But the same method as presently claimed of separating the dienes prior to determining is taught by the Wieland and Vasankari references above. No novelty is seen in selecting known methods of separating and then known methods of determining the separated  
20 material with the expected result.

Claims 1-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The present kit claims are directed to compositions but are claimed as means claims. Compositions cannot properly be described in terms of means or function and must be specifically directly claimed. There may be a typographical error in claim 3. Claim 25 includes limitations regarding instructions which is improper and do not lend patentability to a kit.

The Abstract of the Disclosure is objected to because of legal phraseology and is more than a single paragraph.

Correction is required. See M.P.E.P. § 608.01(b).

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Ahotupa (5,374,313) may be a related case but was not copending with the present application, has the same inventive entity as the present application, and had presently claimed kits restricted out.

Zima (Klin Biochem Metab) teaches determining oxidized LDL's.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.

5 The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on (703) 308-1701. The fax phone number for this Art Unit is (703) 308-4556.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button Patent Electronic Business

15 Center for more information.

Ralph Gitomer  
Primary Examiner  
Group 1623